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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,156	02/13/2006	Marta Rodriguez-Franco	SONN:087US	5874
7590 08/07/2008				
Mark B. Wilson FULBRIGHT & JAWORSKI L.L.P. 600 Congress Avenue, Suite 2400 Austin, TX 78701			EXAMINER PAGE, BRENT T	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 08/07/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/568,156

**Applicant(s)**

RODRIGUEZ-FRANCO ET AL.

**Examiner**

BRENT PAGE

**Art Unit**

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-25 and 27-52 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 23-25 and 27-52 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
4) ☐ Interview Summary (PTO-413)  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_  
Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

The Reply filed by Applicants on 04/07/2008 is hereby acknowledged. The cancellation of claim 26 without prejudice is acknowledged. Claims 23-25 and 27-52 are pending and examined on the merits below. Any objections or rejections not specifically mentioned below are considered hereby withdrawn in response to Applicants' arguments when taken together with the claim amendments.

#### ***Claim Objections***

Claims 23-25 and 27-52 remain objected to because of the following informalities: The claims still contain nonelected subject matter. Appropriate correction is required.

Applicant's arguments filed 04/07/2008 have been fully considered but they are not persuasive.

Applicants urge primarily that the restriction requirement is improper (pages 8-9 of response).

This is not persuasive because the restriction requirement has been made final. Applicant is reminded that once the restriction requirement has been made final, Applicant must file a petition if Applicant believes the restriction requirement is improper. Furthermore, as indicated in the previous office action, the art cited in the lack of unity discloses Moss Expression Promoting Regions, and they are therefore known in the art and as referenced in Applicants filed IDS.

***Claim Rejections - 35 USC § 112***

Claims 23-25 and 27-52 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:13, does not reasonably provide enablement for all nucleus-derived expression promoting regions from all mosses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims remain rejected for the reasons of record in the office action mailed out on 10/05/2007 as well as the reasons set forth below.

Applicant's arguments filed 04/07/2008 have been fully considered but they are not persuasive.

Applicants urge that a person of ordinary skill in the art could make and use the claimed invention without undue experimentation, that one could make an expression promoting fragment without undue experimentation and that these fragments could be screened for expression promoting activity (pages 10-11 of the response).

This is not persuasive because no guidance has been given to enable one to determine what a functioning fragment would look like. No sequences have been described and no function other than 30% of the expression promoting activity of a working heterologous promoter has been given as guidance for which to make functioning embodiments. This guidance is not sufficient for one to make and use the full scope of the claims. For example, 30% of the expression promoting activity of a working heterologous promoter could mean 30% of the expression promoting activity of

a heterologous promoter that promotes only a minimal amount of transcript as it can still be classified as “working” as some level of transcript is detectable. However, such a fragment would barely produce any transcript at all and would generally be recognized in the art to be a non-functioning embodiment, contrary to the broad guidance provided in the specification. Furthermore, although the cauliflower mosaic virus 35S promoter is mentioned as an example for a comparison basis for this expression activity, it is but one example and the examples do not appear to be limited to that promoter, or indeed even a constitutive promoter. For one to be enabled for fragments of a promoter, the promoter activity must be sufficiently characterized for one to be able to determine whether or not they actually have a functioning embodiment. The broad language of the claims, particularly wherein it says “any of” a particular SEQ ID NO: does not even limit the embodiment to contiguous fragments retaining the full promoter activity.

Applicants urge that the cited art on the unpredictability of promoters does not apply to MPERs (page 11 of response).

This is not persuasive because there is no guidance in the specification that gives any indication or in any way teaches that moss expression promoting regions are any different than any other type of promoter. In fact the constant comparison to cauliflower mosaic virus 35S promoter suggests the opposite. If MPERs have special characteristics that render the cited art irrelevant, such characteristics should be fully disclosed to enable one of skill in the art to make and use the invention. Moreover, Applicants' claims are drawn to regions of the promoter that would function to enhance expression in some undefined way, yet Weise et al (2006 Appl. Microbiol. Biotechnol.

70:337-345) teaches that the desired expression features of the elected sequence are only available when the 5' intron is present and that this intron does not maintain its' enhancer like ability when used in a heterologous system absent its' native moss promoter; and thus Applicants have not taught how to make and/or use the broadly claimed promoter fragments (see abstract and in column 1 of page 343 line lines 28-45 of reference).

Claims 23-25 and 27-52 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims remain rejected for the reasons of record in the office action mailed out on 10/05/2007 as well as the reasons set forth below.

Applicant's arguments filed 04/07/2008 have been fully considered but they are not persuasive.

Applicants urge that the claims are supported by written description and that the reliance on Eli Lilly and Amgen is not applicable to the current claims (Pages 12-13 of the response).

This is not persuasive because the claims are sufficiently broad that one of skill in the art would not readily recognize when they are in possession of a functioning versus a non-functioning embodiment. In such a case, the specification must adequately describe the structures that are required for function, particularly wherein the

function is the defining characteristic as to whether or not one is in possession of a particular embodiment of the invention. The specification of the instant invention does not disclose these structures, nor does it describe the defining features of the invention and as such, the claims lack adequate written description for the full scope of the claims.

***Claim Rejections - 35 USC § 102***

The rejections of claims 23-25, 27-28 and 34-35 under 36 USC 102(b) for anticipation is hereby withdrawn in response to Applicants arguments when taken together with the claim amendments.

***Claim Rejections - 35 USC § 103***

The rejections of claims 23-25, 27-28 and 33-52 under 36 USC 103(a) for obviousness is hereby withdrawn in response to Applicants arguments when taken together with the claim amendments.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Russell Kallis/

Primary Examiner, Art Unit 1638



